

Appendix A

First Amended and Supplemental Complaint

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA**

VASCULAR SOLUTIONS LLC,)
TELEFLEX LIFE SCIENCES)
LIMITED, ARROW)
INTERNATIONAL, INC., and) No. 0:19-cv-01760-PJS-TNL
TELEFLEX LLC)
)
Plaintiff,)
) **Jury Trial Demanded**
v.)
)
MEDTRONIC, INC., and)
MEDTRONIC VASCULAR, INC.,)
)
Defendant.

FIRST AMENDED AND SUPPLEMENTAL COMPLAINT

This is a complaint for patent infringement. Vascular Solutions LLC, Teleflex Life Sciences Limited, Arrow International, Inc. (“Arrow”), and Teleflex LLC (collectively “VSI”) bring this action against Defendants Medtronic, Inc., and Medtronic Vascular, Inc. (collectively “Medtronic”) and state as follows.

PARTIES

1. Plaintiff Vascular Solutions LLC is a Minnesota entity with a place of business at 6464 Sycamore Court North, Maple Grove, MN 55369. Together with its affiliated companies, Vascular Solutions LLC develops and manufactures clinical products for use in minimally invasive coronary and peripheral vasculature procedures. Vascular Solutions LLC's innovative products are developed to satisfy the needs of physicians performing complex vascular procedures.

2. As of the filing of the original Complaint, Plaintiff Teleflex Innovations S.à r.l. was a Luxembourg corporation affiliated with Vascular Solutions LLC and the owner of the patents-in-suit. Teleflex Innovations S.à r.l. granted an exclusive license to the patents-in-suit to Vascular Solutions LLC to make, use, offer to sell, and sell products that are covered by the patents-in-suit along with the right to participate in litigation to enforce the patents-in-suit and other rights and obligations as stated in agreements between Vascular Solutions LLC and Teleflex Innovations S.à r.l.

3. Plaintiff Arrow is a Pennsylvania corporation with a place of business at 550 East Swedesford Road, Suite 400, Wayne, PA 19087 and is affiliated with Vascular Solutions LLC and Teleflex Life Sciences Limited. As of the filing of the original Complaint, Vascular Solutions LLC had granted Arrow an exclusive license to offer to sell and sell under the patents-in-suit; a right to participate in litigation to enforce the patents-in-suit; and other rights and obligations as stated in the agreements between Vascular Solutions LLC and Arrow.

4. As of the filing of the original Complaint, Plaintiff Teleflex LLC employed individuals, as part of a service provider relationship with Arrow, that sell products that practice the patents-in-suit. On or about August 5, 2019, Teleflex LLC and Arrow entered into an exclusive distribution agreement.

5. As a result of a merger conducted on or about September 30, 2019, Teleflex Innovations S.à.r.l. merged into and was absorbed by its parent company, Teleflex Medical Devices S.à.r.l., a private limited liability company incorporated under the laws of the Grand-Duchy of Luxembourg. As a result of this merger, the patents-in-suit

became the property of Teleflex Medical Devices S.à.r.l. as successor-in-interest to Teleflex Innovations S.à.r.l.

6. As a result of a subsequent asset transfer conducted on or about December 30, 2019, the patents-in-suit were transferred from Teleflex Medical Devices S.à.r.l. to Teleflex Life Sciences Limited, a limited liability company duly incorporated and validly existing under the laws of Malta, having its registered office at 171, Old Bakery Street, Valletta VLT 1455, Malta. As a consequence of this asset transfer, the patents-in-suit became the property of Teleflex Life Sciences Limited, and Teleflex Life Sciences Limited assumed all the rights and obligations of Teleflex Medical Devices S.à.r.l and its predecessor-in-interest Teleflex Innovations S.à.r.l., including their right to sue and recover for past and future infringements.

7. Effective February 3, 2020, the license agreement between Teleflex Life Sciences Limited and Vascular Solutions LLC and the license agreement between Vascular Solutions LLC and Arrow were terminated by agreement of the parties. Vascular Solutions LLC and Arrow maintained their right to sue for infringement occurring prior to the effective date of the termination agreement.

8. Effective February 3, 2020, Teleflex Life Sciences Limited granted Teleflex LLC an exclusive license to make, have made, use, sell, offer for sale, and import products that are covered by the patents-in-suit along with the right to participate in litigation to enforce the patents-in-suit and other rights and obligations as stated in the agreement between Teleflex Life Sciences Limited and Teleflex LLC.

9. Effective February 3, 2020, Teleflex LLC granted Vascular Solutions LLC an exclusive license to make and have made products that are covered by the patents-in-suit along with the right to participate in litigation to enforce the patents-in-suit and other rights and obligations as stated in the agreement between Teleflex LLC and Vascular Solutions LLC.

10. Defendant Medtronic, Inc. is a Minnesota corporation with a place of business at 710 Medtronic Parkway, Minneapolis, MN 55432.

11. Defendant Medtronic Vascular, Inc. is a Delaware company with a place of business at 3576 Unocal Place, Fountaingrove A, Santa Rosa, CA 95403. Medtronic Vascular, Inc. is registered to do business in Minnesota with a registered business address of 2345 Rice Street, Suite 230, Roseville, MN 55113. The Minnesota Secretary of State Business Record Details identify the Chief Executive Officer of Medtronic Vascular, Inc. as Sean Salmon and list an address for the Chief Executive Officer at 710 Medtronic Parkway, LC300, Minneapolis, MN 55432.

JURISDICTION

12. This action arises under the Patent Act, 35 U.S.C. § 271 *et seq.*

13. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

14. This Court has personal jurisdiction over Defendants. Medtronic, Inc. is incorporated in and is a resident of Minnesota and maintains an office and transacts business within Minnesota. Medtronic Vascular, Inc. is registered to conduct business in

Minnesota, maintains a registered office in Minnesota, and identifies its Chief Executive Officer with an address in Minnesota.

15. Venue is proper in this District under 28 U.S.C. § 1391 and 1400(b). Medtronic, Inc. is incorporated in and is a resident of Minnesota and maintains an office and transacts business within Minnesota. Medtronic Vascular, Inc. is registered to conduct business in Minnesota, maintains a registered office in Minnesota, and identifies its Chief Executive Officer with an address in Minnesota. Medtronic has committed acts of infringement described herein in Minnesota.

MEDTRONIC'S INFRINGING PRODUCTS AND ACTIVITIES

16. Medtronic has committed acts of patent infringement by making, using, selling, offering for sale, and/or importing into the United States a guide extension catheter for interventional cardiology procedures marketed and sold as the Telescope Guide Extension Catheter.

17. Medtronic's Telescope product is available in two sizes: 6F and 7F. When both products are discussed collectively they will be referred to as "Telescope." If referred to separately, they will be referred to as "Telescope 6F" and "Telescope 7F," respectively.

18. Medtronic's Telescope catheter and its uses are a copy of VSI's industry-leading and bestselling interventional product, the GuideLiner catheter, and its uses, and of the patented features of the GuideLiner catheter that resulted in its remarkable success.

19. A copy of Medtronic's in-service slide deck for its Telescope catheter is attached as Exhibit A. Medtronic believes and intends that the product information for the Telescope catheter in Exhibit A is accurate.

20. A copy of Medtronic's Instructions for Use for the Telescope catheter is attached as Exhibit B. Exhibit B is accessible through <https://www.medtronic.com/us-en/healthcare-professionals/products/cardiovascular/coronary-catheters/telescope.html>, which is a link provided on Medtronic's website <https://www.medtronic.com/us-en/index.html>. Medtronic believes and intends that the product information for the Telescope catheter in Exhibit B is accurate.

21. A copy of Medtronic's website page for the Telescope catheter is attached as Exhibit C. Exhibit C is accessible through <https://www.medtronic.com/us-en/healthcare-professionals/products/cardiovascular/coronary-catheters/telescope.html>, which is a link provided on Medtronic's website <https://www.medtronic.com/us-en/index.html>. Medtronic believes and intends that the product information for the Telescope catheter in Exhibit C is accurate.

22. A copy of a Medtronic press release relating to the Telescope catheter dated May 16, 2019 is attached as Exhibit D. Exhibit D is accessible through <http://newsroom.medtronic.com/phoenix.zhtml?c=251324&p=irol-newsArticle&ID=2398888>, which is a link provided on Medtronic's website <https://www.medtronic.com/us-en/index.html>. Medtronic believes and intends that the product information for the Telescope catheter in Exhibit D is accurate.

23. A copy of a letter from the U.S. Food and Drug Administration (“FDA”) to Medtronic concerning Medtronic’s Section 510(k) premarket notification of intent to market the Telescope catheter is attached as Exhibit E. Pages 3 through 7 of Exhibit E were submitted by or on behalf of Medtronic to the FDA and contain a summary of the contents of Medtronic’s Section 510(k) premarket notification of intent to market the Telescope catheter. Medtronic believes and intends that the information concerning the Telescope catheter and Medtronic’s 510(k) premarket notification of intent to market the Telescope catheter are accurate.

24. Exhibit E states that “Medtronic’s Telescope™ Guide Extension Catheter is substantially equivalent to the predicate device based on similarities in intended use and technological characteristics.” Ex. E at 5. Exhibit E identifies the substantially equivalent predicate device as “GuideLiner V3 Catheter.” *Id.*

25. Medtronic advertises its coronary guide catheters on its website, including at least the Launcher Coronary Guide Catheter, the Sherpa NX Active Coronary Guide Catheter, and the Sherpa NX Balanced Coronary Guide Catheter (collectively “Medtronic Guide Catheters”). Exhibit F is a copy of Medtronic’s website <https://www.medtronic.com/us-en/healthcare-professionals/products/cardiovascular/coronary-catheters/guide.html> depicting its coronary guide catheter products. This website is accessible via a link provided on Medtronic’s website <https://www.medtronic.com/us-en/index.html>. Medtronic believes and intends that the product information for its guide catheters in Exhibit F is accurate.

26. In connection with its literature regarding the Telescope catheter, Medtronic promotes its “legacy of market-leading catheter expertise” and refers to itself as a “true market leader . . . [b]ased on guide catheter . . . market share reports and data on file at Medtronic.” Ex. A at 23.

27. A guide catheter is required in order to use Medtronic’s Telescope catheter. *E.g.*, Ex. A at 39 (“Required GC I.D. (in.) . . .”); Ex. B at 5 (“Other items that are required but not provided in the package: Guide catheter”); Ex. E at 5 (“Telescope™ Guide Extension Catheter is intended to be used in conjunction with guide catheters”).

28. Medtronic directs its customers and users of the Telescope guide extension catheter to use Telescope with a guide catheter. *E.g.*, Ex. A at 39 (“Required GC I.D. (in.) . . .”); Ex. B at 4 (“Telescope guide extension catheter is intended to be used in conjunction with guide catheters”) (“The guide extension catheter is designed to act as an extension to a traditional guide catheter”) (“The guide extension catheter is delivered through a guide catheter”), 5 (“Other items that are required but not provided in the package: Guide catheter”); Ex. E at 5 (“Telescope™ Guide Extension Catheter is intended to be used in conjunction with guide catheters”).

29. Medtronic markets its Telescope catheter for the purpose of acting “as an extension to a traditional guide catheter and to facilitate the delivery of interventional devices into the vasculature.” Ex. B at 4; *see also id.* (“Telescope guide extension catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of

interventional devices.”); Ex. E at 5 (“The guide extension catheter is designed to act as an extension to a traditional guide catheter”) (“Telescope™ Guide Extension Catheter is intended to be used in conjunction with guide catheters”).

30. As of at least 2017, Medtronic was aware that VSI had a patent portfolio relating to its GuideLiner catheter.

31. Medtronic asked to discuss a license to VSI’s GuideLiner patent portfolio.

32. VSI declined to license its GuideLiner patent portfolio to Medtronic.

COUNT I

Claim for Patent Infringement of U.S. Patent No. 8,048,032

33. The allegations of paragraphs 1-32 are re-alleged as if fully set forth herein.

34. Teleflex Life Sciences Limited is the owner of United States Patent No. 8,048,032 (“’032 patent”), which issued on November 1, 2011, a copy of which is attached as Exhibit G.

35. Medtronic has infringed and continues to infringe one or more claims of the ’032 patent, including at least claims 12 and 14, under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and importing (directly or through intermediaries), in this District and elsewhere in the United States, guide extension catheters, namely the Telescope guide extension catheter.

36. Attached as Exhibit L is a claim chart showing an example of how Medtronic infringes claims 12 and 14 of the ’032 patent.

37. Medtronic’s Telescope catheter satisfies claim element 11(p), as shown in Exhibit L.

38. Medtronic's Telescope catheter satisfies claim element 11(a), as shown in Exhibit L.

39. Medtronic's Telescope catheter satisfies claim element 11(b), as shown in Exhibit L.

40. Medtronic's Telescope catheter satisfies claim element 11(c), as shown in Exhibit L.

41. Medtronic's Telescope catheter satisfies claim element 11(d), as shown in Exhibit L.

42. Medtronic's Telescope catheter satisfies claim element 11(e), as shown in Exhibit L.

43. Medtronic's Telescope catheter satisfies claim element 12, as shown in Exhibit L.

44. Medtronic's Telescope catheter satisfies claim element 14, as shown in Exhibit L.

45. VSI did not give Medtronic authorization or license to make, use, offer to sell, sell, or import the Telescope catheter.

46. Medtronic also indirectly infringes the '032 patent, including at least claims 12 and 14 under at least 35 U.S.C. § 271(b).

47. Medtronic has induced and continues to induce infringement in this District and elsewhere in the United States of one or more claims of the '032 patent, including at least claims 12 and 14, by, among other things, actively and successfully encouraging, instructing, enabling, and otherwise causing end users and/or customers to use its

Telescope catheter in a manner that infringes the '032 patent. For example, Medtronic's Instructions for Use instruct end users and/or customers to use the Telescope catheter to perform interventional cardiology procedures. *E.g.*, Ex. B at 4 ("The guide extension catheter is designed to act as an extension to a traditional guide catheter and to facilitate the delivery of interventional devices into the vasculature. The guide extension catheter is intended to be used within the coronary and/or peripheral vasculature to provide support."). Medtronic's Instructions for Use, FDA submission, and marketing materials indicate that Telescope is specifically designed to be used with a guide catheter and require that the Telescope catheter be used along with a guide catheter and hemostatic valve. *E.g.*, Ex. A at 11, 39 ("Required GC I.D. (in.) . . ."); Ex. B at 4 ("Telescope guide extension catheter is intended to be used in conjunction with guide catheters . . .") ("The guide extension catheter is designed to act as an extension to a traditional guide catheter . . ."), 5 ("Other items that are required but not provided in the package: Guide catheter . . . Y-adaptor with hemostasis valve"); Ex. E at 5 ("The guide extension catheter is designed to act as an extension to a traditional guide catheter . . .") ("Telescope™ Guide Extension Catheter is intended to be used in conjunction with guide catheters . . ."). End users and/or customers have used the Telescope catheter in a manner that infringes one or more claims of the '032 patent.

48. Upon information and belief, at least as early as February 22, 2019, Medtronic had knowledge of the '032 patent.

49. Medtronic did not develop the Telescope catheter on its own, but instead copied VSI's GuideLiner catheter. Medtronic has willfully infringed and continues to willfully infringe the '032 patent.

50. VSI has satisfied the notice or marking provisions of 35 U.S.C. § 287.

51. Medtronic's infringement of the '032 patent has caused and will continue to cause damage to VSI, causing irreparable harm for which there is no adequate remedy at law, unless enjoined.

COUNT II

Claim for Patent Infringement of U.S. Patent No. RE45,380

52. The allegations of paragraphs 1-51 are re-alleged as if fully set forth herein.

53. Teleflex Life Sciences Limited is the owner of United States Patent No. RE45,380 ("380 Patent"), which issued on February 17, 2015, a copy of which is attached as Exhibit H.

54. Medtronic has infringed and continues to infringe one or more claims of the '380 patent, including at least claims 12, 13, and 15, under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing (directly or through intermediaries), in this District and elsewhere in the United States, a system made up of guide extension catheters, namely the Telescope catheter, and guide catheters, namely the Medtronic Guide Catheters.

55. Attached as Exhibit M is a claim chart showing an example of how Medtronic infringes claims 12, 13, and 15 of the '380 patent.

56. Medtronic's Telescope catheter and/or Medtronic's Guide Catheters satisfy claim element 12(p), as shown in Exhibit M.

57. Medtronic's Telescope catheter and/or Medtronic's Guide Catheters satisfy claim element 12(a), as shown in Exhibit M.

58. Medtronic's Telescope catheter and/or Medtronic's Guide Catheters satisfy claim element 12(b), as shown in Exhibit M.

59. Medtronic's Telescope catheter and/or Medtronic's Guide Catheters satisfy claim element 12(c), as shown in Exhibit M.

60. Medtronic's Telescope catheter and/or Medtronic's Guide Catheters satisfy claim element 12(d), as shown in Exhibit M.

61. Medtronic's Telescope catheter and/or Medtronic's Guide Catheters satisfy claim element 12(e), as shown in Exhibit M.

62. Medtronic's Telescope catheter and/or Medtronic's Guide Catheters satisfy claim element 12(f), as shown in Exhibit M.

63. Medtronic's Telescope catheter and/or Medtronic's Guide Catheters satisfy claim element 12(g), as shown in Exhibit M.

64. Medtronic's Telescope catheter and/or Medtronic's Guide Catheters satisfy claim element 13, as shown in Exhibit M.

65. Medtronic's Telescope catheter and/or Medtronic's Guide Catheters satisfy claim element 15, as shown in Exhibit M.

66. VSI did not give Medtronic authorization or license to make, use, offer to sell, sell, or import the Telescope catheter or a system comprising the Telescope catheter and a Medtronic Guide Catheter.

67. Medtronic also indirectly infringes the '380 patent, including at least claims 12, 13, and 15, under 35 U.S.C. § 271(b) and (c).

68. Upon information and belief, at least as early as February 22, 2019, Medtronic had knowledge of the '380 patent.

69. Medtronic has induced and continues to induce infringement in this District and elsewhere in the United States of one or more claims of the '380 patent, including at least claims 12, 13, and 15, by, among other things, actively and successfully encouraging, instructing, enabling, and otherwise causing end users and/or customers to use its Telescope catheter along with Medtronic Guide Catheters and/or third-party guide catheters, and a hemostatic valve as a system which infringes the '380 patent. For example, Medtronic's Instructions for Use instruct end users and/or customers to use the Telescope catheter along with a guide catheter and hemostatic valve to perform interventional cardiology procedures. *E.g.*, Ex. B at 4 ("The guide extension catheter is designed to act as an extension to a traditional guide catheter and to facilitate the delivery of interventional devices into the vasculature. The guide extension catheter is intended to be used within the coronary and/or peripheral vasculature to provide support.") ("Open the hemostasis valve and advance the guide extension catheter through the hemostasis valve and into the guide catheter."). Medtronic's Instructions for Use, FDA submission, and marketing materials indicate that Telescope is specifically designed to be used with a

guide catheter and require that the Telescope catheter be used along with a guide catheter and hemostatic valve. *E.g.*, Ex. A at 11, 39 (“Required GC I.D. (in.) . . .”); Ex. B at 4 (“Telescope guide extension catheter is intended to be used in conjunction with guide catheters . . .”) (“The guide extension catheter is designed to act as an extension to a traditional guide catheter . . .”), 5 (“Other items that are required but not provided in the package: Guide catheter . . . Y-adaptor with hemostasis valve”); Ex. E at 5 (“The guide extension catheter is designed to act as an extension to a traditional guide catheter . . .”) (“TelescopeTM Guide Extension Catheter is intended to be used in conjunction with guide catheters . . .”). End users and/or customers have used the Telescope catheter as part of a system that infringes one or more claims of the ’380 patent.

70. Medtronic has contributed to and continues to contribute to the infringement of one or more claims of the ’380 patent, including at least claims 12, 13, and 15, by importing into the United States (directly or through intermediaries) and/or offering to sell and selling (directly or through intermediaries), to end users and/or customers, in this District and elsewhere in the United States, its Telescope catheter, a product that constitutes a component of a system covered by the ’380 patent. Upon information and belief, Medtronic knows its products are especially made or especially adapted for use in an infringement and that there is no substantial non-infringing use for a Telescope catheter without a guide catheter and a hemostatic valve. *E.g.*, Ex. A at 11, 39 (“Required GC I.D. (in.) . . .”); Ex. B at 4 (“Telescope guide extension catheter is intended to be used in conjunction with guide catheters . . .”) (“The guide extension catheter is designed to act as an extension to a traditional guide catheter . . .”), 5 (“Other

items that are required but not provided in the package: Guide catheter . . . Y-adaptor with hemostasis valve”); Ex. E at 5 (“The guide extension catheter is designed to act as an extension to a traditional guide catheter”) (“TelescopeTM Guide Extension Catheter is intended to be used in conjunction with guide catheters”). The Telescope catheter constitutes a material part of the invention, and end users and/or customers have used the Telescope catheter as part of a system that infringes one or more claims of the ’380 patent.

71. Medtronic did not develop the Telescope catheter on its own, but instead copied VSI’s GuideLiner catheter. Medtronic has willfully infringed and continues to willfully infringe the ’380 patent.

72. VSI has satisfied the notice or marking provisions of 35 U.S.C. § 287.

73. Medtronic’s infringement of the ’380 patent has caused and will continue to cause damage to VSI, causing irreparable harm for which there is no adequate remedy at law, unless enjoined.

COUNT III

Claim for Patent Infringement of U.S. Patent No. RE45,776

74. The allegations of paragraphs 1-73 are re-alleged as if fully set forth herein.

75. Teleflex Life Sciences Limited is the owner of United States Patent No. RE45,776 (“’776 Patent”), which issued on October 27, 2015, a copy of which is attached as Exhibit I.

76. Medtronic has infringed and continues to infringe one or more claims of the ’776 patent, including at least claims 25, 36, and 37, under 35 U.S.C. § 271(a) by making,

using, offering to sell, selling, and importing (directly or through intermediaries), in this District and elsewhere in the United States, guide extension catheters, namely the Telescope catheter.

77. Attached as Exhibit N is a claim chart showing an example of how Medtronic infringes claims 25, 36, and 37 of the '776 patent.

78. Medtronic's Telescope catheter satisfies claim element 25(p), as shown in Exhibit N.

79. Medtronic's Telescope catheter satisfies claim element 25(a), as shown in Exhibit N.

80. Medtronic's Telescope catheter satisfies claim element 25(b), as shown in Exhibit N.

81. Medtronic's Telescope catheter satisfies claim element 25(c), as shown in Exhibit N.

82. Medtronic's Telescope catheter satisfies claim element 25(d), as shown in Exhibit N.

83. Medtronic's Telescope catheter satisfies claim element 36, as shown in Exhibit N.

84. Medtronic's Telescope catheter satisfies claim element 37, as shown in Exhibit N.

85. VSI did not give Medtronic authorization or license to make, use, offer to sell, sell, or import the Telescope catheter.

86. Medtronic also indirectly infringes the '776 patent, including at least claims 25, 36, and 37 under at least 35 U.S.C. § 271(b).

87. Upon information and belief, at least as early as February 22, 2019, Medtronic had knowledge of the '776 patent.

88. Medtronic has induced and continues to induce infringement in this District and elsewhere in the United States of one or more claims of the '776 patent, including at least claims 25, 36, and 37, by, among other things, actively and successfully encouraging, instructing, enabling, and otherwise causing end users and/or customers to use its Telescope catheter in a manner that infringes the '776 patent. For example, Medtronic's Instructions for Use instruct end users and/or customers to use the Telescope catheter to perform interventional cardiology procedures. *E.g.*, Ex. B at 4 ("The guide extension catheter is designed to act as an extension to a traditional guide catheter and to facilitate the delivery of interventional devices into the vasculature. The guide extension catheter is intended to be used within the coronary and/or peripheral vasculature to provide support."). Medtronic's Instructions for Use, FDA submission, and marketing materials indicate that Telescope is specifically designed to be used with a guide catheter and require that the Telescope catheter be used along with a guide catheter. *E.g.*, Ex. A at 39 ("Required GC I.D. (in.) . . ."); Ex. B at 4 ("Telescope guide extension catheter is intended to be used in conjunction with guide catheters . . .") ("The guide extension catheter is designed to act as an extension to a traditional guide catheter . . ."), 5 ("Other items that are required but not provided in the package: Guide catheter . . ."); Ex. E at 5 ("The guide extension catheter is designed to act as an extension to a traditional guide

catheter”) (“TelescopeTM Guide Extension Catheter is intended to be used in conjunction with guide catheters”). End users and/or customers have used the Telescope catheter in a manner that infringes one or more claims of the ’776 patent.

89. Medtronic did not develop the Telescope catheter on its own, but instead copied VSI’s GuideLiner catheter. Medtronic has willfully infringed, and continues to willfully infringe, the ’776 patent.

90. VSI has satisfied the notice or marking provisions of 35 U.S.C. § 287.

91. Medtronic’s infringement of the ’776 patent has caused and will continue to cause damage to VSI, causing irreparable harm for which there is no adequate remedy at law, unless enjoined.

COUNT IV

Claim for Patent Infringement of U.S. Patent No. RE47,379

92. The allegations of paragraphs 1-91 are re-alleged as if fully set forth herein.

93. Teleflex Life Sciences Limited is the owner of United States Patent No. RE47,379 (“’379 Patent”), which issued on May 7, 2019, a copy of which is attached as Exhibit J.

94. Medtronic has infringed and continues to infringe one or more claims of the ’379 patent, including at least claims 25, 33, 34, 38, and 44, under 35 U.S.C. § 271(g) by importing into the United States and/or offering to sell, selling, or using (directly or through intermediaries), in this District and elsewhere in the United States, guide extension catheters, namely Telescope guide extension catheters that are made by a process patented in the United States.

95. Attached as Exhibit O is a claim chart showing an example of how Medtronic infringes claims 25, 33, 34, 38, and 44 of the '379 patent.

96. Manufacture of Medtronic's Telescope catheter satisfies claim element 25(p), as shown in Exhibit O.

97. Manufacture of Medtronic's Telescope catheter satisfies claim element 25(a), as shown in Exhibit O.

98. Manufacture of Medtronic's Telescope catheter satisfies claim element 25(b), as shown in Exhibit O.

99. Manufacture of Medtronic's Telescope catheter satisfies claim element 25(c), as shown in Exhibit O.

100. Manufacture of Medtronic's Telescope catheter satisfies claim element 25(d), as shown in Exhibit O.

101. Manufacture of Medtronic's Telescope catheter satisfies claim element 25(e), as shown in Exhibit O.

102. Manufacture of Medtronic's Telescope catheter satisfies claim element 25(f), as shown in Exhibit O.

103. Manufacture of Medtronic's Telescope catheter satisfies claim element 25(g), as shown in Exhibit O.

104. Manufacture of Medtronic's Telescope catheter satisfies claim element 33, as shown in Exhibit O.

105. Manufacture of Medtronic's Telescope 6F catheter satisfies claim element 34, as shown in Exhibit O.

106. Manufacture of Medtronic's Telescope catheter satisfies claim element 38(p), as shown in Exhibit O.

107. Manufacture of Medtronic's Telescope catheter satisfies claim element 38(a), as shown in Exhibit O.

108. Manufacture of Medtronic's Telescope catheter satisfies claim element 38(b), as shown in Exhibit O.

109. Manufacture of Medtronic's Telescope catheter satisfies claim element 38(c), as shown in Exhibit O.

110. Manufacture of Medtronic's Telescope catheter satisfies claim element 38(d), as shown in Exhibit O.

111. Manufacture of Medtronic's Telescope catheter satisfies claim element 38(e), as shown in Exhibit O.

112. Manufacture of Medtronic's Telescope catheter satisfies claim element 44, as shown in Exhibit O.

113. VSI did not give Medtronic authorization or license to use, offer to sell, sell, or import the Telescope catheter.

114. Medtronic also indirectly infringes the '379 patent, including at least claims 25, 33, 34, 38, and 44 under 35 U.S.C. § 271(b) and claims 33 and 34 under 35 U.S.C. § 271(c).

115. At least as of the date of the filing of the original complaint, July 2, 2019, Medtronic had knowledge of the '379 patent.

116. Medtronic has induced and continues to induce infringement in this District and elsewhere in the United States of one or more claims of the '379 patent, including at least claims 25, 33, 34, 38, and 44, by, among other things, actively and successfully encouraging, instructing, enabling, and otherwise causing end users and/or customers to use its Telescope catheter in a manner that infringes the '379 patent. For example, Medtronic's Instructions for Use instruct end users and/or customers to use the Telescope catheter to perform interventional cardiology procedures. *E.g.*, Ex. B at 4 ("The guide extension catheter is designed to act as an extension to a traditional guide catheter and to facilitate the delivery of interventional devices into the vasculature. The guide extension catheter is intended to be used within the coronary and/or peripheral vasculature to provide support."). Medtronic's Instructions for Use, FDA submission, and marketing materials indicate that Telescope is specifically designed to be used with a guide catheter and require that the Telescope catheter be used along with a guide catheter. *E.g.*, Ex. A at 39 ("Required GC I.D. (in.) . . ."); Ex. B at 4 ("Telescope guide extension catheter is intended to be used in conjunction with guide catheters . . .") ("The guide extension catheter is designed to act as an extension to a traditional guide catheter . . ."), 5 ("Other items that are required but not provided in the package: Guide catheter . . ."); Ex. E at 5 ("The guide extension catheter is designed to act as an extension to a traditional guide catheter . . .") ("TelescopeTM Guide Extension Catheter is intended to be used in conjunction with guide catheters . . ."). End users and/or customers have used the Telescope catheter in a manner that infringes one or more claims of the '379 patent.

117. Medtronic has contributed to and continues to contribute to the infringement of one or more claims of the '379 patent, including at least claims 33 and 34, by importing into the United States (directly or through intermediaries) and/or offering to sell and selling (directly or through intermediaries), to end users and/or customers, in this District and elsewhere in the United States, its Telescope catheter, a product that constitutes a component of a combination or system covered by the '379 patent. Upon information and belief, Medtronic knows its products are especially made or especially adapted for use in an infringement and that there is no substantial non-infringing use for a Telescope catheter without a guide catheter. *E.g.*, Ex. A at 39 (“I.D. (in.)...0.056”...“Required GC I.D. (in.)...6F \geq 0.070”, “I.D. (in.)...0.062”...“Required GC I.D. (in.)...7F \geq 0.078”); Ex. B at 4 (“Telescope guide extension catheter is intended to be used in conjunction with guide catheters”) (“The guide extension catheter is designed to act as an extension to a traditional guide catheter”) (“The guide extension catheter is offered in sizes compatible with 6 Fr and 7 Fr guide catheters”) (“The guide extension catheter is delivered through a guide catheter resulting in an overall inner diameter that is approximately 1 Fr smaller than the guide catheter.”), 5 (“Other items that are required but not provided in the package: Guide catheter”); Ex. E at 5 (“The guide extension catheter is designed to act as an extension to a traditional guide catheter”) (“Telescope™ Guide Extension Catheter is intended to be used in conjunction with guide catheters”). The Telescope catheter constitutes a material part of the invention, and end users and/or customers have used the Telescope

catheter, along with a guide catheter and/or a Medtronic Guide Catheter as part of a combination that infringes one or more claims of the '379 patent.

118. Medtronic did not develop the Telescope catheter on its own, but instead copied VSI's GuideLiner catheter. Medtronic has willfully infringed and continues to willfully infringe, the '379 patent.

119. VSI has satisfied the notice or marking provisions of 35 U.S.C. § 287.

120. Medtronic's infringement of the '379 patent has caused and will continue to cause damage to VSI, causing irreparable harm for which there is no adequate remedy at law, unless enjoined.

COUNT V
Claim for Patent Infringement of U.S. Patent No. RE45,760

121. The allegations of paragraphs 1-120 are re-alleged as if fully set forth herein.

122. Teleflex Life Sciences Limited is the owner of United States Patent No. RE45,760 ("760 Patent"), which issued on October 20, 2015, a copy of which is attached as Exhibit K.

123. Medtronic has infringed and continues to infringe one or more claims of the '760 patent, including at least claims 25, 28, 29, 32, and 48, under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing (directly or through intermediaries), in this District and elsewhere in the United States, a system made up of guide extension catheters, namely the Telescope 6F catheter, and guide catheters, namely Medtronic Guide Catheters.

124. Attached as Exhibit P is a claim chart showing an example of how Medtronic infringes claims 25, 28, 29, 32, and 48 of the '760 patent.

125. Medtronic's Telescope 6F catheter and/or Medtronic's Guide Catheters satisfy claim element 25(p), as shown in Exhibit P.

126. Medtronic's Telescope 6F catheter and/or Medtronic's Guide Catheters satisfy claim element 25(a), as shown in Exhibit P.

127. Medtronic's Telescope 6F catheter and/or Medtronic's Guide Catheters satisfy claim element 25(b), as shown in Exhibit P.

128. Medtronic's Telescope 6F catheter and/or Medtronic's Guide Catheters satisfy claim element 25(c), as shown in Exhibit P.

129. Medtronic's Telescope 6F catheter and/or Medtronic's Guide Catheters satisfy claim element 25(d), as shown in Exhibit P.

130. Medtronic's Telescope 6F catheter and/or Medtronic's Guide Catheters satisfy claim element 25(e), as shown in Exhibit P.

131. Medtronic's Telescope 6F catheter and/or Medtronic's Guide Catheters satisfy claim element 25(f), as shown in Exhibit P.

132. Medtronic's Telescope 6F catheter and/or Medtronic's Guide Catheters satisfy claim element 28, as shown in Exhibit P.

133. Medtronic's Telescope 6F catheter and/or Medtronic's Guide Catheters satisfy claim element 29, as shown in Exhibit P.

134. Medtronic's Telescope 6F catheter and/or Medtronic's Guide Catheters satisfy claim element 32, as shown in Exhibit P.

135. Medtronic's Telescope 6F catheter and/or Medtronic's Guide Catheters satisfy claim element 48(p), as shown in Exhibit P.

136. Medtronic's Telescope 6F catheter and/or Medtronic's Guide Catheters satisfy claim element 48(a), as shown in Exhibit P.

137. Medtronic's Telescope 6F catheter and/or Medtronic's Guide Catheters satisfy claim element 48(b), as shown in Exhibit P.

138. Medtronic's Telescope 6F catheter and/or Medtronic's Guide Catheters satisfy claim element 48(c), as shown in Exhibit P.

139. Medtronic's Telescope 6F catheter and/or Medtronic's Guide Catheters satisfy claim element 48(d), as shown in Exhibit P.

140. Medtronic's Telescope 6F catheter and/or Medtronic's Guide Catheters satisfy claim element 48(e), as shown in Exhibit P.

141. Medtronic's Telescope 6F catheter and/or Medtronic's Guide Catheters satisfy claim element 48(f), as shown in Exhibit P.

142. VSI did not give Medtronic authorization or license to make, use, offer to sell, sell, or import the Telescope 6F catheter or a system comprising the Telescope 6F catheter and a Medtronic Guide Catheter.

143. Medtronic also indirectly infringes the '760 patent, including at least claims 25, 28, 29, 32, and 48, under 35 U.S.C. § 271(b) and (c).

144. Upon information and belief, at least as early as February 22, 2019, Medtronic had knowledge of the '760 patent.

145. Medtronic has induced and continues to induce infringement in this District and elsewhere in the United States of one or more claims of the '760 patent, including at least claims 25, 28, 29, 32, and 48, by, among other things, actively and successfully encouraging, instructing, enabling, and otherwise causing end users and/or customers to use its Telescope 6F catheter along with Medtronic Guide Catheters and/or third-party guide catheters, and a hemostasis valve as a system which infringes the '760 patent. For example, Medtronic's Instructions for Use instruct end users and/or customers to use the Telescope 6F catheter along with a guide catheter and hemostatic valve to perform interventional cardiology procedures. *E.g.*, Ex. B at 4 ("The guide extension catheter is designed to act as an extension to a traditional guide catheter and to facilitate the delivery of interventional devices into the vasculature. The guide extension catheter is intended to be used within the coronary and/or peripheral vasculature to provide support.") ("Open the hemostasis valve and advance the guide extension catheter through the hemostasis valve and into the guide catheter."). Medtronic's Instructions for Use, FDA submission, and marketing materials indicate that Telescope is specifically designed to be used with a guide catheter where Telescope has a lumen having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter, and require that the Telescope catheter be used along with such a guide catheter. *E.g.*, Ex. A at 11, 39 ("I.D. (in.)...0.056"... "Required GC I.D. (in.)...6F \geq 0.070"); Ex. B at 4 ("Telescope guide extension catheter is intended to be used in conjunction with guide catheters . . .") ("The guide extension catheter is designed to act as an extension to a traditional guide catheter .

...”) (“The guide extension catheter is offered in sizes compatible with 6 Fr and 7 Fr guide catheters....”) (“The guide extension catheter is delivered through a guide catheter resulting in an overall inner diameter that is approximately 1 Fr smaller than the guide catheter.”), 5 (“Other items that are required but not provided in the package: Guide catheter . . . Y-adaptor with hemostasis valve”); Ex. E at 5 (“The guide extension catheter is designed to act as an extension to a traditional guide catheter . . .”) (“TelescopeTM Guide Extension Catheter is intended to be used in conjunction with guide catheters . . .”). End users and/or customers have used the Telescope 6F catheter as part of a system that infringes one or more claims of the ’760 patent.

146. Medtronic has contributed to and continues to contribute to the infringement of one or more claims of the ’760 patent, including at least claims 25, 28, 29, 32, and 48, by importing into the United States (directly or through intermediaries) and/or offering to sell and selling (directly or through intermediaries), to end users and/or customers, in this District and elsewhere in the United States, its Telescope 6F catheter, a product that constitutes a component of a combination or system covered by the ’760 patent. Upon information and belief, Medtronic knows its products are especially made or especially adapted for use in an infringement and that there is no substantial non-infringing use for a Telescope 6F catheter without a guide catheter where Telescope has a lumen having a uniform cross-sectional inner diameter that is not more than one French size smaller than the cross-sectional inner diameter of the lumen of the guide catheter, and a hemostatic valve. *E.g.*, Ex. A at 11, 39 (“I.D. (in.)...0.056”...“Required GC I.D. (in.)...6F \geq 0.070”); Ex. B at 4 (“Telescope guide extension catheter is intended to be

used in conjunction with guide catheters”) (“The guide extension catheter is designed to act as an extension to a traditional guide catheter”) (“The guide extension catheter is offered in sizes compatible with 6 Fr and 7 Fr guide catheters....”) (“The guide extension catheter is delivered through a guide catheter resulting in an overall inner diameter that is approximately 1 Fr smaller than the guide catheter.”), 5 (“Other items that are required but not provided in the package: Guide catheter . . . Y-adaptor with hemostasis valve”); Ex. E at 5 (“The guide extension catheter is designed to act as an extension to a traditional guide catheter”) (“Telescope™ Guide Extension Catheter is intended to be used in conjunction with guide catheters”). The Telescope 6F catheter constitutes a material part of the invention, and end users and/or customers have used the Telescope catheter as part of a system that infringes one or more claims of the ’760 patent.

147. Medtronic did not develop the Telescope catheter on its own, but instead copied VSI’s GuideLiner catheter. Medtronic has willfully infringed and continues to willfully infringe, the ’760 patent.

148. VSI has satisfied the notice or marking provisions of 35 U.S.C. § 287.

149. Medtronic’s infringement of the ’760 patent has caused and will continue to cause damage to VSI, causing irreparable harm for which there is no adequate remedy at law, unless enjoined.

COUNT VI

Claim for Patent Infringement of U.S. Patent No. 8,142,413

150. The allegations of paragraphs 1-149 are re-alleged as if fully set forth herein.

151. Teleflex Life Sciences Limited is the owner of United States Patent No. 8,142,413 (“’413 Patent”), which issued on March 27, 2012, a copy of which is attached as Exhibit S.

152. Medtronic has indirectly infringed and continues to indirectly infringe one or more claims of the ’413 patent, including at least claim 7, under 35 U.S.C. § 271(b) and (c).

153. Attached hereto as Exhibit T is a claim chart showing an example of how Medtronic’s Telescope catheter has been and is used to infringe claim 7 of the ’413 patent.

154. Medtronic’s Telescope catheter is used to satisfy claim element 1(p), as shown in Exhibit T.

155. Medtronic’s Telescope catheter is used to satisfy claim element 1(a), as shown in Exhibit T.

156. Medtronic’s Telescope catheter is used to satisfy claim element 1(b), as shown in Exhibit T.

157. Medtronic’s Telescope catheter is used to satisfy claim element 1(c), as shown in Exhibit T.

158. Medtronic's Telescope catheter is used to satisfy claim element 1(d), as shown in Exhibit T.

159. Medtronic's Telescope catheter is used to satisfy claim element 1(e), as shown in Exhibit T.

160. Medtronic's Telescope catheter is used to satisfy claim element 1(f), as shown in Exhibit T.

161. Medtronic's Telescope catheter is used to satisfy claim element 7, as shown in Exhibit T.

162. VSI did not give Medtronic authorization or license to make, use, offer to sell, sell, or import the Telescope catheter for use in or as part of any method.

163. Upon information and belief, at least as early as February 22, 2019, Medtronic had knowledge of the '413 patent.

164. Medtronic has induced and continues to induce infringement in this District and elsewhere in the United States of one or more claims of the '413 patent, including at least claim 7, by, among other things, actively and successfully encouraging, instructing, enabling, and otherwise causing end users and/or customers to use its Telescope catheter along with Medtronic Guide Catheters and/or third-party guide catheters, a guidewire, a hemostasis valve, and an interventional cardiology device as part of a method that infringes the '413 patent. For example, Medtronic's Telescope marketing materials and Instructions for Use instruct end users and/or customers to use the Telescope catheter for providing backup support, including resisting axial and shear forces, for an interventional cardiology device in the coronary vasculature and to use it with a guidewire and a guide

catheter having a continuous lumen extending for a predefined length from a proximal end at a hemostatic valve to a distal end adapted to be placed in a branch artery. *See* Ex. T. Medtronic's Telescope marketing materials and Instructions for Use instruct end users and/or customers to use the Telescope catheter with a guide catheter having a lumen and a distal end that is advanced over a guidewire and through a first artery so that the distal end of the guide catheter is positioned in a branch artery off from the first artery. *See* Ex. T. Medtronic's Telescope marketing materials and Instructions for Use instruct end users and/or customers to use the Telescope catheter so that a flexible tip portion defining a tubular structure of Telescope having a circular cross-section and a length that is shorter than a continuous lumen of a guiding catheter with which it is used is advanced into the continuous lumen of the guiding catheter. *See* Ex. T. Medtronic's Telescope marketing materials and Instructions for Use instruct end users and/or customers to use the Telescope catheter so that a substantially rigid portion of Telescope that is proximal of and operably connected to a flexible tip portion defining a tubular structure, more rigid along a longitudinal axis than the flexible tip portion, and defining a rail structure without a lumen, is inserted into the continuous lumen of the guiding catheter. *See* Ex. T. Medtronic's Telescope marketing materials and Instructions for Use indicate that Telescope is specifically designed so that the combined length of Telescope's substantially rigid portion and the flexible tip portion is greater than the length of the continuous lumen of the guide catheter. *See* Ex. T. Medtronic's Telescope Instructions for Use instruct end users and/or customers to use the Telescope catheter so that a distal portion of the flexible tip portion of Telescope is advanced beyond the distal end of the

guide catheter and into the second artery such that the distal portion extends into a second artery and such that at least a portion of the proximal portion of the substantially rigid portion extends proximally through the hemostatic valve. *See* Ex. T. Medtronic's Telescope marketing materials and Instructions for Use instruct end users and/or customers to use the Telescope catheter so that interventional cardiology devices are inserted into and through the continuous lumen of the guide catheter alongside the substantially rigid portion of Telescope and advanced through and beyond the lumen of the flexible tip portion into contact with or past a lesion in a second artery. *See* Ex. T. Medtronic's Telescope marketing materials and Instructions for Use instruct end users and/or customers to use the Telescope catheter so that a distal portion of the tubular structure of Telescope is extended beyond the distal end of the standard guide catheter with which it is used while a proximal portion of Telescope remains within the lumen of the standard guide catheter, such that Telescope assists in resisting axial and shear forces exerted when an interventional cardiology device is passed through and beyond the coaxial lumen that would otherwise tend to dislodge the standard catheter from the branch artery. *See* Ex. T. End users and/or customers have used the Telescope catheter as part of a method that infringes one or more claims of the '413 patent.

165. Medtronic has contributed to and continues to contribute to the infringement of one or more claims of the '413 patent, including at least claim 7, by importing into the United States (directly or through intermediaries) and/or offering to sell and selling (directly or through intermediaries), to end users and/or customers, in this District and elsewhere in the United States, its Telescope catheter, a product for use in

practicing the patented method covered by the '413 patent. Upon information and belief, Medtronic knows its Telescope catheter is especially made or especially adapted for use in an infringement and that there is no substantial non-infringing use for a Telescope catheter. *E.g.* Ex. B at 4 (“The Telescope guide extension catheter is a single-lumen rapid exchange catheter. The guide extension catheter is designed to act as an extension to a traditional guide catheter and to facilitate the delivery of interventional devices into the vasculature. The guide extension catheter is intended to be used within the coronary and/or peripheral vasculature to provide support.”); *id.* (“Telescope guide extension catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices.”); Ex. B at 5 (“3. Under fluoroscopy, advance the guide extension catheter beyond the distal tip of the guide catheter and into the designed location within the vessel. 4. Use fluoroscopy to confirm the desired position of the guide extension catheter in the vessel. 5. If performing an interventional procedure, backload the interventional device over the existing guidewire. Advance the device through the guide catheter and guide extension catheter into the desired vascular space. 6. Tighten the Y-adaptor hemostasis valve securely on the proximal shaft of the guide extension catheter to prevent back-bleeding.”); *id.* (“Do not advance the guide extension catheter more than 15 cm beyond the tip of the guide catheter”); Ex. A at 20 (showing Medtronic “Resolute OnyxTM DES traveling along the on-ramp toward the entry port” of Telescope); Ex. C at 4 (“After positioning a GEC, the ability to deliver stents, balloons, and other interventional devices through the catheter is critical.”); Ex. D

(“Telescope(TM) Guide Extension Catheter, a newly designed catheter used to provide additional backup support and access to distal lesions. Guide extension catheters help deliver coronary stents, balloons and other interventional devices during angioplasty procedures that help to restore blood flow through the coronary and peripheral arteries.”) The Telescope catheter constitutes a material part of the invention, and end users and/or customers have used the Telescope catheter as part of a method that infringes one or more claims of the ’413 patent.

166. Medtronic did not develop the Telescope catheter on its own, or the method of using the Telescope catheter on its own, but instead copied VSI’s GuideLiner catheter and its method of use. Medtronic has willfully infringed and continues to willfully infringe, the ’413 patent.

167. VSI has satisfied the notice or marking provisions of 35 U.S.C. § 287.

168. Medtronic’s infringement of the ’413 patent has caused and will continue to cause damage to VSI, causing irreparable harm for which there is no adequate remedy at law, unless enjoined.

COUNT VII

Claim for Patent Infringement of U.S. Patent No. RE46,116

169. The allegations of paragraphs 1-168 are re-alleged as if fully set forth herein.

170. Teleflex Life Sciences Limited is the owner of United States Patent No. RE46,116 (“’116 Patent”), which issued on August 23, 2016, a copy of which is attached as Exhibit U.

171. Medtronic has indirectly infringed and continues to indirectly infringe one or more claims of the '116 patent, including at least claim 46, under 35 U.S.C. § 271(b) and (c).

172. Attached hereto as Exhibit V is a claim chart showing an example of how Medtronic's 6F Telescope catheter has been and is used to infringe claim 46 of the '116 patent.

173. Medtronic's 6F Telescope catheter is used to satisfy claim element 25(p), as shown in Exhibit V.

174. Medtronic's 6F Telescope catheter is used to satisfy claim element 25(a), as shown in Exhibit V.

175. Medtronic's 6F Telescope catheter is used to satisfy claim element 25(b), as shown in Exhibit V.

176. Medtronic's 6F Telescope catheter is used to satisfy claim element 25(c), as shown in Exhibit V.

177. Medtronic's 6F Telescope catheter is used to satisfy claim element 45, as shown in Exhibit V.

178. Medtronic's 6F Telescope catheter is used to satisfy claim element 46, as shown in Exhibit V.

179. VSI did not give Medtronic authorization or license to make, use, offer to sell, sell, or import the Telescope catheter for use in or as part of any method.

180. Upon information and belief, at least as early as February 22, 2019, Medtronic had knowledge of the '116 patent.

181. Medtronic has induced and continues to induce infringement in this District and elsewhere in the United States of one or more claims of the '116 patent, including at least claim 46, by, among other things, actively and successfully encouraging, instructing, enabling, and otherwise causing end users and/or customers to use its Telescope 6F catheter along with Medtronic Guide Catheters and/or third-party guide catheters, a hemostasis valve, and a stent or balloon catheter as part of a method that infringes the '116 patent. For example, Medtronic's Telescope marketing materials and Instructions for Use instruct end users and/or customers to use the Telescope 6F catheter with a guiding catheter having a lumen, a distal end of which is advanced through a main blood vessel to an ostium of a coronary artery. *See* Ex. V. Medtronic's Telescope marketing materials and Instructions for Use instruct end users and/or customers to use the Telescope 6F catheter so that a distal end of a tubular structure of Telescope 6F is advanced through and beyond the distal end of the guide catheter while a segment defining a side opening, which extends for a distance along a longitudinal axis and is accessible from a longitudinal side defined transverse to the longitudinal axis to receive interventional cardiology devices when positioned within the lumen of the guiding catheter, remains within the lumen of the guide catheter. *See* Ex. V. Medtronic's Telescope marketing materials and Instructions for Use indicate that Telescope is specifically designed so that the tubular structure of Telescope 6F has a cross-sectional inner diameter that is not more than one French size smaller than a cross-sectional inner diameter of the lumen of the guide catheter with which it is used. *See* Ex. V. Medtronic's Telescope marketing materials and Instructions for Use instruct end

users and/or customers to use the Telescope 6F so that while maintaining a position of the distal end of Telescope 6F beyond the distal end of the guiding catheter, a balloon catheter or stent is advanced at least partially through the guiding catheter and Telescope 6F and into the coronary artery. *See* Ex. V. Medtronic's Telescope marketing materials and Instructions for Use instruct end users and/or customers to use the Telescope 6F so that the balloon catheter or stent is advanced through a hemostatic valve associated with a proximal end of the guiding catheter, along a substantially rigid segment of Telescope 6F, through the side opening of Telescope 6F, and through the tubular structure of Telescope 6F. *See* Ex. V. Medtronic's Telescope marketing materials indicate that Telescope 6F is specifically designed so that the substantially rigid portion is rigid enough to allow the device to be advanced within the guide catheter. *See* Ex. V. Medtronic's Telescope marketing materials instruct end users and/or customers to use the Telescope 6F so that advancing the balloon catheter or stent at least partially through the side opening of Telescope 6F includes advancing the balloon catheter or stent through a side-opening structure in Telescope 6F having at least two inclined slopes. *See* Ex. V. Medtronic's Telescope marketing materials indicate that Telescope 6F is specifically designed so that the opening, which is formed from a "rigid" polymer while the tube is formed from a "flexible" polymer, is more rigid than a material or material combination forming the tubular structure. *See* Ex. V. End users and/or customers have used the Telescope 6F catheter as part of a method that infringes one or more claims of the '116 patent.

182. Medtronic has contributed to and continues to contribute to the infringement of one or more claims of the '116 patent, including at least claim 46, by

importing into the United States (directly or through intermediaries) and/or offering to sell and selling (directly or through intermediaries), to end users and/or customers, in this District and elsewhere in the United States, its Telescope 6F catheter, a product for use in practicing the patented method covered by the '116 patent. Upon information and belief, Medtronic knows its Telescope catheter is especially made or especially adapted for use in an infringement and that there is no substantial non-infringing use for a Telescope 6F catheter. *E.g.* Ex. B at 4 (“The Telescope guide extension catheter is a single-lumen rapid exchange catheter. The guide extension catheter is designed to act as an extension to a traditional guide catheter and to facilitate the delivery of interventional devices into the vasculature. The guide extension catheter is intended to be used within the coronary and/or peripheral vasculature to provide support.”); *id.* (“Telescope guide extension catheter is intended to be used in conjunction with guide catheters to access discrete regions of the coronary and/or peripheral vasculature, and to facilitate placement of interventional devices.”); Ex. B at 5 (“3. Under fluoroscopy, advance the guide extension catheter beyond the distal tip of the guide catheter and into the designed location within the vessel. 4. Use fluoroscopy to confirm the desired position of the guide extension catheter in the vessel. 5. If performing an interventional procedure, backload the interventional device over the existing guidewire. Advance the device through the guide catheter and guide extension catheter into the desired vascular space. 6. Tighten the Y-adaptor hemostasis valve securely on the proximal shaft of the guide extension catheter to prevent back-bleeding.”); *id.* (“Do not advance the guide extension catheter more than 15 cm beyond the tip of the guide catheter”); Ex. A at 20 (showing Medtronic

“Resolute OnyxTM DES traveling along the on-ramp toward the entry port” of Telescope); Ex. A at 10 (showing and describing the “Flexible TruFlex soft polymer tip”, “Flexible polymer in main jacket”, “Rigid polymer in proximal jacket”); *id.* at 19 (showing and describing “Stiff polymer at the entry port”); *id.* at 28 (showing tip and describing “TruFlex tip is made via extrusion of a soft polymer specifically selected to responsively deflect and provide flexibility”); Ex. C at 4 (“After positioning a GEC, the ability to deliver stents, balloons, and other interventional devices through the catheter is critical.”); Ex. D (“Telescope(TM) Guide Extension Catheter, a newly designed catheter used to provide additional backup support and access to distal lesions. Guide extension catheters help deliver coronary stents, balloons and other interventional devices during angioplasty procedures that help to restore blood flow through the coronary and peripheral arteries.”) The Telescope 6F catheter constitutes a material part of the invention, and end users and/or customers have used the Telescope 6F catheter as part of a method that infringes one or more claims of the ’116 patent.

183. Medtronic did not develop the Telescope catheter on its own, or the method of using the Telescope catheter on its own, but instead copied VSI’s GuideLiner catheter and its method of use. Medtronic has willfully infringed and continues to willfully infringe, the ’116 patent.

184. VSI has satisfied the notice or marking provisions of 35 U.S.C. § 287.

185. Medtronic’s infringement of the ’116 patent has caused and will continue to cause damage to VSI, causing irreparable harm for which there is no adequate remedy at law, unless enjoined.

PRAYER FOR RELIEF

VSI respectfully requests the following relief:

- A. A judgment that Medtronic has infringed the '032, '380, '776, '379, '760, '413, and '116 patents;
- B. A judgment and order requiring Medtronic to pay all appropriate damages under 35 U.S.C. § 284, including pre-judgment and post-judgment interest, costs, and increased damages for Medtronic's willful infringement;
- C. A judgment and order that this is an exceptional case under 35 U.S.C. § 285 and awarding VSI its reasonable attorney fees;
- D. Preliminary and permanent injunctions against Medtronic and its officers, agents, employees, attorneys, and all persons in active concert or participation with them, prohibiting infringement of the '032, '380, '776, '379, '760, '413, and '116 patents; and
- E. Such other and further relief that this Court may deem just and equitable.

DEMAND FOR A JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, VSI demands a trial by jury of all issues so triable.

Dated: January 31, 2020

s/ J. Derek Vandenburg

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